09-11-00

A

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of: Weimin Sun et al.
Title: IMPROVED RATE-ADAPTIVE THERAPY WITH AUTOMATIC LIMITING OF MAXIMUM PACING RATE
Attorney Docket No.: 279.279US1

PATENT APPLICATION TRANSMITTAL

BOX PATENT APPLICATION
Commissioner for Patents
Washington, D.C. 20231

We are transmitting herewith the following attached items and information (as indicated with an "X"):

X Return postcard.
X Utility Patent Application under 37 CFR § 1.53(b) comprising:
X Specification (22 pgs, including claims numbered 1 through 25 and a 1 page Abstract).
X Drawing(s) (7 sheets).
X Unsigned Combined Declaration and Power of Attorney (4 pgs).

The filing fee (NOT ENCLOSED) will be calculated as follows:

	No. Filed	No. Extra	Rate	Fee
TOTAL CLAIMS	25 - 20 =	5	x 18 =	**$90.00**
INDEPENDENT CLAIMS	3 - 3 =	0	x 78 =	**$0.00**
MULTIPLE DEPENDENT CLAIMS PRESENTED				**$0.00**
BASIC FEE				**$690.00**
TOTAL				**$780.00**

THE FILING FEE WILL BE PAID UPON RECEIPT OF THE NOTICE TO FILE MISSING PARTS.

SCHWEGMAN, LUNDBERG, WOESSNER & KLUTH, P.A.
P.O. Box 2938, Minneapolis, MN 55402 (612-373-6900)

By: _____
Atty: Timothy E. Bianchi
Reg. No. 39,610

Customer Number 21186

"Express Mail" mailing label number: EL618436194US
Date of Deposit: September 8, 2000

EL618436194US

This paper or fee is being deposited on the date indicated above with the United States Postal Service pursuant to 37 CFR 1.10, and is addressed to the Commissioner for Patents, Box Patent Application, Washington, D.C. 20231.

IMPROVED RATE-ADAPTIVE THERAPY WITH AUTOMATIC LIMITING OF MAXIMUM PACING RATE

Field of the Invention

This invention pertains to systems and methods for cardiac rhythm management. In particular, the invention relates to a system and method for automatically adjusting the operating parameters of a rate-adaptive cardiac pacemaker.

Background

A conventional cardiac pacemaker is an implantable battery-powered electronic device that responds to sensed cardiac events and elapsed time intervals by changing its functional states so as to properly interpret sensed data and deliver pacing pulses to the heart at appropriate times. The pacing pulses are delivered through a lead made up of electrodes on a catheter or wire that connects the pacemaker to the heart. Some electronic devices, called implantable cardioverter-defibrillators, are capable of delivering electrical shocks, rather than small-intensity pacing stimuli, in order to cardiovert or defibrillate the heart. The term "pacemaker" as used herein, however, should be taken to mean both pacemakers and any device with a pacemaking function, such as an implantable cardioverter/defibrillator with a pacemaker incorporated therein.

Pacemakers can generally operate in a variety of modes, generally designated by a letter code of three positions where each letter in the code refers to a specific function of the pacemaker. The first letter refers to which heart chambers are paced and which may be an A (for atrium), a V (for ventricle), D (for both chambers), or O (for none). The second letter refers to which chambers are sensed by the pacemaker's sensing channels and uses the same letter designations as used for pacing. The third letter refers to the pacemaker's response to a sensed P wave from the atrium or an R wave from the ventricle and may be an I (for inhibited), T (for triggered), D (for dual in which both triggering and inhibition are used), and O (for no response). Modern pacemakers are typically programmable so that they can operate in any mode which the physical configuration of the device will allow. Additional sensing of physiological data allows some pacemakers to change the rate at which they pace the heart in accordance with some parameter correlated to metabolic demand. Such pacemakers, which are the primary

subject of the present invention, are called rate-adaptive pacemakers and are designated by a fourth letter added to the three-letter code, R.

The most common condition for which pacemakers are used is the treatment of bradycardia. Permanent pacing for bradycardia is indicated in patients with symptomatic bradycardia of any type as long as it is likely to be permanent or recurrent and is not associated with a transient condition from which the patient may recover. Atrio-ventricular conduction defects (i.e., AV block) that are fixed or intermittent and sick sinus syndrome represent the most common indications for permanent pacing. In chronotropically competent patients in need of ventricular pacing, atrial triggered modes such as DDD or VDD are desirable because they allow the pacing to track the physiologically normal atrial rhythm, which causes cardiac output to be responsive to the metabolic needs of the body. Atrial triggering modes are contraindicated, however, in patients prone to atrial fibrillation or flutter or in whom a reliable atrial sense cannot be obtained. In the former case, the ventricles will be paced at too high a rate. Failing to sense an atrial P wave, on the other hand, results in a loss of atrial tracking which can lead to negative hemodynamic effects because the pacemaker then reverts to its minimum ventricular pacing rate. In pacemaker patients who are chronotropically incompetent (e.g., sinus node dysfunction) or in whom atrial-triggered modes such as DDD and VDD are contraindicated, the heart rate is dictated solely by the pacemaker in the absence of faster intrinsic cardiac activity. That pacing rate is determined by the programmed escape intervals of the pacemaker and is referred to as the lower rate limit or LRL.

Pacing the heart at a fixed rate as determined by the LRL setting of the pacemaker, however, does not allow the heart rate to increase with increased metabolic demand. Cardiac output is determined by two factors, the stroke volume and heart rate, with the latter being the primary determinant. Although stroke volume can be increased during exercise (e.g., due to increased venous return and increased myocardial contractility), the resulting increase in cardiac output is usually not sufficient to meet the body's metabolic needs unless the heart rate is also increased. If the heart is paced at a constant rate, as for example by a VVI pacemaker, severe limitations are imposed upon the patient with respect to lifestyle and activities. It is to overcome these limitations and

improve the quality of life of such patients that rate-adaptive pacemakers have been developed.

The body's normal regulatory mechanisms act so as to increase cardiac output when the metabolic rate is increased due to an increased exertion level in order to transport more oxygen and remove more waste products. One way to control the rate of a pacemaker, therefore, is to measure the metabolic rate of the body and vary the pacing rate in accordance with the measurement. Metabolic rate can effectively be directly measured by, for example, sensing blood pH or blood oxygen saturation. Practical problems with implementing pacemakers controlled by such direct measurements, however, have led to the development of pacemakers that are rate-controlled in accordance with physiological variables that are indirectly reflective of the body's metabolic rate such as body temperature or respiratory rate. (See, e.g., U.S. Patent No. 5,376,106 issued to Stahmann et al. and assigned to Cardiac Pacemakers, Inc., the disclosure of which is hereby incorporated by reference.) Measuring respiratory rate, for example, estimates oxygen consumption. A better approximation to oxygen consumption is the minute ventilation, however, which is the product of ventilation rate and tidal volume. An even more indirect measurement of metabolic rate is the measurement of body activity or motion with either an accelerometer or vibration sensor. The activity-sensing pacemaker uses an accelerometer or microphone-like sensor inside the pacemaker case that responds to motion or mechanical vibrations of the body by producing electrical signals proportional to the patient's level of physical activity. More complex rate-responsive systems incorporate multiple sensors that compensate for the deficits of specific individual sensors. All of the above-mentioned sensors, however, are for the purpose of ascertaining the exertion level of the patient and changing the heart rate in accordance therewith.

In such rate-adaptive pacemakers that vary the pacing rate in accordance with a measured exertion level, the control system is generally implemented as an open-loop controller that maps a particular exertion level to one particular heart rate, termed the sensor-indicated rate (SIR). Various parameters are set in order to fit the control system to the individual patient, including minimal and maximal heart rate and responsiveness. Minimal and maximal heart rate settings are primarily for patient safety, and the

responsiveness of the pacemaker determines how much change in heart rate results from a given change in exertion level. An under-responsive pacemaker will unnecessarily limit exercise duration and intensity in the patient because the heart rate will not increase enough to match metabolic demand, while an over-responsive pacemaker will lead to palpitations and patient discomfort. Control parameters are generally set in conventional rate-adaptive pacemakers after implantation and during clinical visits according to a fixed formula or as a result of exercise testing. There is a need for rate-adaptive pacemakers that automatically adjust control parameters in accordance with a patient's changing physical condition so as to reduce the need for follow-up clinical visits and extensive testing.

Summary of the Invention

The present invention relates to a system and method for automatically adjusting the responsiveness of a rate-adaptive pacemaker using exertion level measurements. In a particular implementation of the pacemaker, measured exertion levels in the patient are mapped to a pacing rate by a rate response curve. The responsiveness of a rate-adaptive pacemaker depends upon four endpoint settings of the rate response curve that define its dynamic range: the minimum pacing rate, the resting exertion level, the maximum exercise capacity or long-term maximum exertion level, and the maximum sensor-indicated rate MSR. In one embodiment, daily maximum exertion levels are collected for a specified time period and used to update the long-term maximum exertion level. The slope of the rate response curve is then adjusted in order for the updated long-term maximum exertion level to be mapped to a specified maximum sensor indicated rate.

In accordance with the invention, the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate that is independent from a specified maximum sensor indicated rate. The specified maximum sensor indicated rate then limits the rate mapped by the rate response curve to a specified maximum value. As the patient's maximum exercise capacity as defined by a long-term maximum exertion level is automatically determined by collecting maximum measured exertion levels over a specified period of time, the specified maximum sensor indicated rate can be increased to

equal the rate at which the rate response curve maps the long-term maximum exertion level to.

Brief Description of the Drawings

Fig. 1A is a block diagram of a rate-adaptive pacemaker.

Fig. 1B is a diagram of a single-slope rate response curve.

Fig. 2 shows values of $SIR_{DailyMax}$ plotted for each day of the week.

Fig. 3 shows the slope change of the rate response curve in response to changes in the average sensor indicated rate.

Figs. 4 and 5 show how changes in the fitness level of the patient change the slope of the rate response curve.

Fig. 6 shows the values of $EXL_{DailyMax}$ plotted for each day of the week and how the ranges of $EXL_{DailyMax}$ are mapped to daily maximum exertion level heart rate $EXR_{DailyMax}$ values.

Detailed Description

A particular implementation of a rate-adaptive pacemaker as shown in Fig. 1A. As used herein, the term pacemaker should be taken to mean any cardiac rhythm management device with a pacing functionality including an implantable cardioverter/defibrillator that includes a pacemaker. A pacemaker controller senses cardiac events through a sensing channel and outputs pacing pulses to the heart via a pacing channel in accordance with a programmed pacing mode. A microprocessor serves as the controller in this embodiment and communicates with a memory 12 via a bidirectional data bus 13. The memory 12 typically comprises a ROM or RAM for program storage and a RAM for data storage. The pacemaker has atrial sensing and pacing channels comprising electrode 34, lead 33, sensing amplifier 31, pulse generator 32, and an atrial channel interface 30 which communicates bidirectionally with a port of microprocessor 10. The device also has ventricular sensing and pacing channels comprising electrodes 24, leads, sensing amplifier 21, pulse generator 22, and ventricular channel interface 20. For each channel, the same lead and electrode are used for both sensing and pacing. The channel interfaces 20 and 30 include analog-to-digital

converters for digitizing sensing signal inputs from the sensing amplifiers and registers which can be written to by the microprocessor in order to output pacing pulses, change the pacing pulse amplitude, and adjust the gain and threshold values for the sensing amplifiers. A telemetry interface 40 is also provided for communicating with an external programmer. A minute ventilation sensor MVS and an accelerometer AC are employed to sense the minute ventilation and body activity, respectively. The pacemaker uses the sensed minute ventilation and/or the accelerometer signal to adjust the rate at which the pacemaker paces the heart in the absence of a faster intrinsic rhythm. The microprocessor 10 executes programmed instructions that implement various pacing and rate-adaptive algorithms, including the method described below.

The responsiveness of a rate-adaptive pacemaker is controlled in accordance with a rate-response curve RRC such as shown in Fig. 1B. Other embodiments may use a dual-slope curve or a non-linear curve. A change in exertion level as determined from a minute ventilation measurement causes a proportional change in the sensor indicated rate in accordance with the slope of the curve, termed the response factor RF. The sensor indicated rate is then used as a lower rate limit (LRL) by the pacemaker to pace the heart in accordance with a programmed pacing mode. The LRL is the rate at which the heart is paced in the absence of faster intrinsic activity. As shown in the figure, the rate response curve maps a resting exertion level REL to a minimum sensor indicated rate MinHR which corresponds to the minimum LRL that is to be used by the pacemaker. The maximum sensor indicated rate MaxHR is the maximum rate at which the pacemaker is allowed to pace the heart and is mapped to by the rate response curve from the maximum exertion level the patient is expected to be able to reach, referred to as the maximum exercise capacity MEC. In the single-slope rate response curve shown in Fig. 1B, the response factor RF may then be defined as:

$$RF = (MaxHR - MinHR) / (MEC - REL)$$

The responsiveness of the pacemaker can also be controlled in accordance with a dual-slope rate response curve such as shown in Fig. 3. A change in exertion level EXL (as determined from either minute ventilation or body activity) causes a change in the sensor indicated rate that is proportional to the slope of the response curve. The slope of the rate response curve is designated the initial response factor RF below the heart rate

breakpoint HRB, and designated the high rate response factor HRRF above HRB. The heart rate breakpoint HRB ideally should be set to correspond to an exertion level equal to the anaerobic threshold AT of the patient. The anaerobic threshold is the level of exertion above which the concentration of lactic acid produced by anaerobic metabolism starts to build up rapidly in the blood. It thus represents an exertion level at which the body starts to utilize oxygen less efficiently and, along with maximal oxygen consumption, is a useful index of current physical conditioning. The responsiveness of the pacemaker below the anaerobic threshold as defined by RF is greater than that above the threshold as defined by HRRF so that overpacing above the anaerobic threshold is avoided.

The endpoints of any rate response curve are defined by a long-term maximum exertion level $EXL_{LongTermMax}$ corresponding the patient's maximum exercise capacity which is mapped to the maximum sensor indicated rate MSR, and a minimum exertion level EXL_{Min} corresponding to a null EXL signal (i.e., rest) which is mapped to the minimum LRL. The minimum LRL is equal to the lower rate limit LRL setting of pacemaker with no rate adaptation.

The initial values of the parameters RF, HRRF, HRB, long-term maximum exertion level $EXL_{LongTermMax}$, and maximum sensor indicated rate MSR can be specified at the time of pacemaker implant. The initial long-term maximum exertion level is set to the exertion level which is mapped to the MSR by the initial rate response curve or set to a value based upon population data with the other parameters adjusted accordingly. The MSR is usually set to be equivalent to the age-predicted maximum heart rate MAR and limits the pacing rate of the pacemaker to protect against excessively rapid pacing, which would be especially detrimental in patients with coronary artery disease. The MSR may therefore in some cases be set to a value lower than the age-predicted maximum heart rate MAR depending upon the patient's medical condition. A sensor target rate STR may also be specified to represent a heart rate demand corresponding to a particular exertion level. The STR is used as a reference by the pacemaker control system to adjust the rate response curve so that the sensor target rate is reached when the patient exercises at the particular exertion level. As described below, the STR may be updated periodically to represent a heart rate demand corresponding to a maximum exertion level attained during

a specified period (e.g., daily) and is compared with a maximum sensor indicated rate during the same specified period to adjust the rate response curve.

The initial values of $EXL_{LongTermMax}$ and HRB can be determined from formulas dependent upon the patient's age, while the initial STR can be determined by a formula dependent upon a desired target heart rate during exercise and a specified exercise frequency as prescribed by a physician at the time of implant. These parameters can be left fixed unless reprogrammed by a physician during a follow-up clinical visit, but this method of setting control parameters suffers from a number of limitations. First, the patient's maximum exercise capacity $EXL_{LongTermMax}$ and physiological heart rate at the anaerobic threshold HRB depend not only on age, but also upon the physical conditioning of the patient. Also, the STR and exercise frequency prescribed by the physician may not match the patient's actual exercise activity and metabolic heart rate demand (i.e., the heart rate that results in a cardiac output sufficient to meet metabolic needs). If the STR prescribed at implant is less than the patient's actual metabolic heart rate demand, the patient will only be paced at the prescribed STR and will never reach the required rate. If the STR is greater than the actual metabolic heart rate demand, on the other hand, overpacing will occur. Finally, in the initial setting of the parameters, no account is taken of how the patient's exercise activity and exercise capacity may change over time.

In accordance with the invention, the control system automatically adjusts the STR and $EXL_{LongTermMax}$ from initially set values in accordance with measurements of periodic maximum exertion levels attained by the patient as measured by a minute ventilation or activity sensor. Periodic maximum sensor indicated rates are also collected for comparison with the STR in order to adjust the response factor RF. Such periodic maximum exertion levels and sensor indicated rates are preferably collected on a daily basis, and a weekly average of the daily maximums is then used for weekly parameter adjustment. Other time periods for collection, averaging, or updating could, of course, be used. As used herein, therefore, the terms daily and weekly when referring to such periods should be construed broadly so as to also include any similar time periods found to be convenient. In addition, sensor measurements and sensor indicated rates are preferably moving averaged over a specified averaging period (where the averaging period may range, for example, from 30 seconds to 5 minutes) in order to smooth the data

and filter out any spurious signals. In a particular embodiment, the exertion level signals EXL are automatically collected by the device and moving averaged over a one minute averaging period. The maximum among the collected moving averages is then set equal to the daily maximum exertion level $EXL_{DailyMax}$, which is registered and stored. The daily maximum sensor indicated rate is similarly determined. The daily maximum exertion level $EXL_{DailyMax}$ can then be averaged over a specified time period with the resulting average maximum exertion level also registered and stored, e.g., on a weekly basis to result in a weekly average value $Week\_Avg(EXL_{DailyMax})$.

The long-term maximum exertion level $EXL_{LongTermMax}$ is updated in accordance with stored measurements of the patient's daily maximum exertion levels at periodic intervals (e.g., every three months, six months, or year). The maximum value among the stored daily maximum exertion levels measured over the specified long-term period is thus registered and stored as $EXL_{LongTermMax}$. The STR is updated weekly based upon the weekly average of the daily maximum exertion levels $EXL_{DailyMax}$ and the current value of $EXL_{LongTermMax}$. Since the STR is automatically adjusted, an initial setting that does not correspond to the patient's true physiological heart rate demand during exercise will be corrected so that the patient will not be locked to an inappropriate rate. The control system can then use the updated STR and/or $EXL_{LongTermMax}$ values to adjust the slope of the rate response curve (i.e., RF and/or HRRF) and the HRB. Automatically adjusting both the rate response curve slope and HRB thus obviates the need for the physician to attempt to calculate the most appropriate parameter values at the time of implantation or during follow-up. The responsiveness of the pacemaker will then be reflective of the patient's individual exertion levels, and will also automatically adjust in response to changes in the patient's functional capacity or level of physical conditioning. The patient's exertion level and exercise capacity history is also stored and able to be retrieved by a clinician in order to assess both the patient and the functioning of the pacemaker.

The STR is determined from an average of daily maximal exertion level heart rates $EXR_{DailyMax}$ over a specified period. The daily maximal exertion level heart rate $EXR_{DailyMax}$ approximates the heart rate demand corresponding to the daily maximum exertion level $EXL_{DailyMax}$. The daily maximum exertion level heart rate $EXR_{DailyMax}$ is

thus a function of the daily maximal exertion level $EXL_{DailyMax}$ and is determined in this embodiment in accordance with the following table that maps ranges of $EXL_{DailyMax}$ values relative to $EXL_{LongTermMax}$ to an $EXR_{DailyMax}$ value expressed relative to the MAR:

$EXL_{DailyMax}$		$EXR_{DailyMax}$ (in bpm)
80-100% of $EXL_{LongTermMax}$	=	90% of MAR
50-80% of $EXL_{LongTermMax}$	=	70% of MAR
< 50% of $EXL_{LongTermMax}$	=	90 bpm

In other embodiments, rather than comparing $EXL_{DailyMax}$ with discrete thresholds of $EXL_{LongTermMax}$, the daily maximum exertion level heart rate $EXR_{DailyMax}$ may be expressed as a continuous function of the daily maximal exertion level $EXL_{DailyMax}$, $EXL_{LongTermMax}$, and the MAR:

$$EXR_{DailyMax} = (EXL_{DailyMax} / EXL_{LongTermMax}) \, MAR$$

In a presently preferred embodiment, the STR is computed as a weekly average of daily maximum exertion level heart rates.

The daily maximum sensor indicated rate SIR is also moving averaged over the same period as the exertion level signals EXL, with the daily maximum moving average value $SIR_{DailyMax}$ being registered and stored. The $SIR_{DailyMax}$ values are averaged in this embodiment on a weekly basis to result in the average maximal sensor indicated rate $Week\_Avg(SIR_{DailyMax})$. The weekly average maximal sensor indicated rate $Week\_Avg(SIR_{DailyMax})$ is compared with the STR on a weekly basis to control the adjustment of the response factor RF (i.e., the slope of the rate response curve). If the STR is higher than the $Week\_Avg(SIR_{DailyMax})$, the RF will be increased by one step; if the STR is lower, the RF will be decreased by one step. The HRRF may then either be updated as a percentage of the RF or in accordance with an updated $EXL_{LongTermMax}$ value.

The HRB is initially set to a value above the LRL equal to 60% of the rate reserve, where the rate reserve is the amount by which a patient's age-predicted maximum heart rate MAR exceeds the LRL. In one embodiment the HRB is maintained as a fixed percentage of the rate reserve as initially set. In another embodiment, the HRB is a dynamic percentage of the rate reserve such that if the long-term maximal exertion

level $EXL_{LongTermMax}$ (i.e., the patient's peak exercise capacity) is increased due to exercise or fitness training, the HRB is increased proportionately to the increase in the long-term maximal exertion level. The HRB is thus determined from a formula based upon both the patient's age and peak exertion level, which is more indicative of the patient's actual physiological heart rate demand at the anaerobic threshold than a formula based upon age alone. In an exemplary embodiment, for the first three months after implant the long-term maximal exertion level is started with a value equal to the upper limit of maximal exertion levels measured from a similar patient population, or with a value mapped from the initial RF, HRB, HRRF, and age-predicted maximum heart rate MAR. The initial long-term maximal exertion level $EXL_{LongTermMax}$ is maintained for three months unless updated by a measured $EXL_{DailyMax}$ value that is higher.

In the specific embodiment detailed below, the STR is periodically adjusted in accordance with updated weekly averages of the daily maximum exertion level heart rate $EXR_{DailyMax}$. The $EXL_{LongTermMax}$ is also updated in accordance with weekly averages of the patient's maximum exertion levels. A minimum value for $EXL_{LongTermMax}$, designated $EXL_{LongTermMaxMin}$, is determined from population data, the rate response function, and the age-predicted maximum heart rate MAR. In this embodiment, the HRB is maintained at the initialized value, and the HRRF is maintained as a constant percentage of the RF. The method steps are divided into three phases: initialization, daily monitoring, and weekly updating:

Initialization:

MSR = (220 - age);
MAR= max(220-age,MSR);
LRL = 60;
HRB = LRL + 0.6*(MAR-LRL)
RF = 5 (for a minute ventilation signal MV) or RF = 8 (for an activity signal XL);
$EXL_{LongTermMax}$ = average maximal exertion value taken from population data;
$EXL_{LongTermMaxMin}$ = max (MAR/(1.3*RF), population average minimum value);
HRRF = .7 * RF;

Daily Monitoring:

Compute 1 minute moving averages of EXL and SIR signals and store maximum;
$EXL_{DailyMax}$ = maximum moving average value of EXL computed during the day;
$SIR_{DailyMax}$ = maximum moving average value of SIR computed during the day;

Weekly Parameter updating:

Compute Week_Avg($SIR_{DailyMax}$) and Week_Avg($EXL_{DailyMax}$);
$EXL_{LongTermMax}$ = max (Week_Avg($EXL_{DailyMax}$)averaged over 3 mos., $EXL_{LongTermMaxMin}$);
STR = (F_{rest}*90 + F_{mild}*0.7*MAR + $F_{vigorous}$*0.9*MAR)/7
where F_{rest} = (number of days $EXL_{DailyMax}$ is less than 50% of $EXL_{LongTermMax}$)
F_{mild} = (number of days $EXL_{DailyMax}$ is between 50% and 80% of $EXL_{LongTermMax}$)
$F_{vigorous}$ = (number of days $EXL_{DailyMax}$ is over 80% of $EXL_{LongTermMax}$);
If Week_Avg($SIR_{DailyMax}$) < STR then RF is increased by one step (e.g. 15%);
If Week_Avg($SIR_{DailyMax}$) > STR then RF is decreased by one step (e.g. 15%);
HRRF = .7 * RF;

In addition, an initial optimization procedure may be performed for a specified period (e.g., 6 months) in order to optimize the initial settings of the control parameters used by the algorithm. In a first such optimization procedure, the patient first exercises for a one-hour period with the parameters set as follows:

After first hour:
$EXL_{LongTermMax}$ = max($EXL_{LongTermMaxMin}$, (1+B) * $EXL_{FirstHourMax}$)
where $EXL_{FirstHourMax}$ is the maximal exertion level during the hour of exercise and B is a selected buffering factor (e.g., 1,.33, or 0);
Every hour:
If $EXL_{DailyMax}$ > $EXL_{LongTermMax}$
then increase $EXL_{LongTermMaxMin}$ by one step (e.g., 15%);
RF = (HRB - LRL)/(0.5* $EXL_{LongTermMaxMin}$);
Every week:
If (1+B)*$EXL_{DailyMax}$< $EXL_{LongTermMax}$ and $EXL_{LongTermMax}$>$EXL_{LongTermMaxMin}$
then decrease $EXL_{LongTermMaxMin}$ by one step (e.g., 15%);
RF = (HRB - LRL)/(0.5* $EXL_{LongTermMaxMin}$);

In a second optimization procedure, the following steps are performed with no preceding exercise period:

Initial setting:
MSR = LRL + .75*(MAR-LRL);
For second month:
MSR = LRL + .90*(MAR-LRL);
For third through sixth months:
MSR = LRL + (MAR-LRL);
Every hour:
If $EXL_{DailyMax}$ > S* $EXL_{LongTermMax}$

then increase $EXL_{LongTermMaxMin}$ by one step (e.g., 15%);
$RF = (HRB - LRL)/(0.5* EXL_{LongTermMaxMin})$;
where S = 85% for first month and 100% for next five months;
Every week:
If $(1+B)*EXL_{DailyMax} < EXL_{LongTermMax}$ and $EXL_{LongTermMax} > EXL_{LongTermMaxMin}$
then decrease $EXL_{LongTermMaxMin}$ by one step (e.g., 15%);
$RF = (HRB - LRL)/(0.5* EXL_{LongTermMax})$;

In a second specific embodiment, the method steps are similarly divided into three phases: initialization, daily monitoring, and weekly updating.

Initialization:

MAR = (220 - age);
LRL = 60;
HRB = LRL + 0.6*(MAR-LRL);
RF = 5 (for a minute ventilation signal MV) or RF = 8 (for an activity signal XL);
$EXL_{LongTermMax}$ = average maximal exertion value taken from population data;
$EXL_{LongTermMaxMin}$ = max (MAR/(1.3*RF), population average minimum value);
HRRF = determined such that $EXL_{LongTermMax}$ maps to MAR;

Daily Monitoring:

Compute 1-3 minute moving averages of EXL and SIR signals and store maximum;
$EXL_{DailyMax}$ = maximum moving average value of EXL computed during the day;
$SIR_{DailyMax}$ = maximum moving average value of SIR computed during the day;

Weekly parameter updating:

$EXL_{LongTermMax} = \max (EXL_{DailyMax}, EXL_{LongTermMaxMin})$;
Compute $Week\_Avg(SIR_{DailyMax})$ and $Week\_Avg(EXL_{DailyMax})$;
HRB is adjusted proportionate to the change in $EXL_{LongTermMax}$ such that
$HRB = LRL + (0.6 + \text{percentage change in } EXL_{LongTermMax}) *(MAR-LRL)$;
$STR = (F_{rest}*90 + F_{mild}*0.7*MAR + F_{vigorous}*0.9*MAR)/7$
where F_{rest} = (number of days $EXL_{DailyMax}$ is less than 50% of $EXL_{LongTermMax}$)
F_{mild} = (number of days $EXL_{DailyMax}$ is between 50% and 80% of $EXL_{LongTermMax}$)
$F_{vigorous}$ = (number of days $EXL_{DailyMax}$ is over 80% of $EXL_{LongTermMax}$);
If $Week\_Avg(SIR_{DailyMax}) < STR$ then RF is increased by one step;
If $Week\_Avg(SIR_{DailyMax}) > STR$ then RF is decreased by one step;
$HRRF = \min (RF, (MAR - HRB)/(EXL_{LongTermMax} - HRB/RF))$;

During first 6 months after implant, the following steps are also performed:
If $EXL_{DailyMax} > EXL_{LongTermMax}$
then $(EXL_{LongTermMax} = 1.1* EXL_{DailyMax})$;
If $EXL_{DailyMax} > EXL_{LongTermMax}$
then $(EXL_{LongTermMax} = \max(0.9*EXL_{LongTermMax}, \text{Min}(EXL_{LongTermMax}))$;

Figs. 2 through 5 illustrate the operation of the methods just described. Fig. 2 shows values of $SIR_{DailyMax}$ plotted for each day of the week. The average value of $SIR_{DailyMax}$ for the week Week_Avg($SIR_{DailyMax}$) is also shown along with the sensor target rate STR. As can be seen, Week_Avg($SIR_{DailyMax}$) exceeds the STR, so the slope of the rate response curve RF is reduced by one step. Fig. 3 shows the result of the slope change where curve 30 has adjusted to curve 31. The system has been made less responsive in order to compensate for the average sensor indicated rate exceeding the sensor target rate during the past week. If the Week_Avg($SIR_{DailyMax}$) had been less than the STR, the slope of the rate responsive curve would have been increased by one step to make the system more responsive. Note that in this example, both STR and HRB are left unchanged, but are mapped to different exertion levels due to the change in slope of the rate response curve. The high rate response factor may be further adjusted to map the patient's long-term maximum exertion level to the specified maximum sensor indicated rate

Figs. 4 and 5 show how the method responds to changes in the fitness level of the patient as reflected by changes in the long-term maximal exertion level $EXL_{LongTermMax}$. The rate response curve is dynamically adjusted in response to changes in $EXL_{LongTermMax}$ by adjusting the curve so that $EXL_{LongTermMax}$ is mapped to the patient's maximum heart rate MAR (or MSR). In Fig. 5, the initial rate response curve 40 is adjusted to curve 41 when the $EXL_{LongTermMax}$ value is decreased, and adjusted to curve 42 when the $EXL_{LongTermMax}$ value is increased. In this example, the heart rate breakpoint HRB is maintained as a constant percentage of the rate reserve and so is left unchanged as $EXL_{LongTermMax}$ changes. Fig. 5 shows how the HRB value may instead be computed as a dynamic percentage of the rate reserve that depends upon the value of $EXL_{LongTermMax}$. As $EXL_{LongTermMax}$ decreases due to deconditioning, initial rate response curve 50 is adjusted to curve 51. The heart rate breakpoint in this embodiment is also adjusted in accordance with the formula given above so that it decreases, which is reflective of the fact that the anaerobic threshold decreases with decreasing fitness levels. Similarly, if $EXL_{LongTermMax}$ is increased due to an increased fitness level, rate response curve 50 adjusts to curve 52, and the HRB parameter increases.

For safety reasons, it may be desirable in certain embodiments to implement the system described above such that $EXL_{LongTermMax}$ is only increased in response to changes in the patient's physical conditioning and never decreased. That is, once the patient achieves a certain $EXL_{LongTermMax}$, it is assumed that the patient's maximum exercise capacity will not decrease from that level. This prevents the $EXL_{LongTermMax}$ from being decreased simply by the patient going for a long period without exercising maximally and thereby subjecting the patient to overpacing.

Fig. 6 shows the values of $EXL_{DailyMax}$ plotted for each day of the week and an indication on the exertion level axis showing how the ranges of $EXL_{DailyMax}$ are mapped to daily maximum exertion level heart rate $EXR_{DailyMax}$ values. These values are then used to adjust the STR value in accordance with the formula given above. The daily average exertion level for each day is also shown for comparison.

As described above, the responsiveness of a rate-adaptive pacemaker depends upon four endpoint settings that define its dynamic range: the minimum pacing rate, the resting exertion level, the maximum exercise capacity or long-term maximum exertion level, and the maximum sensor-indicated rate MSR. In clinical practice, the MSR is programmed relatively low by most physicians. This is because the dynamic range of an optimized rate-response curve varies from patient to patient, and the rate-response curve may take several weeks to reach a favorable degree of responsiveness with automatic parameter adjustment as the patient's maximum exercise capacity is determined from exertion level measurements. Unless the MSR is conservatively set, the patient may experience severe overpacing during this period. Furthermore, many pacemaker patients suffer from some degree of coronary artery disease, and overpacing in this situation is especially hazardous due to an insufficient myocardial oxygen supply. A disadvantage of initially setting the MSR to a low value, however, is that the patient's exercise capacity is significantly compromised. Since the patient's maximum exercise capacity is usually mapped to the MSR by the rate response curve, the patient will never reach an appropriate paced heart rate when exercising maximally. More importantly, a low MSR will also decrease the responsiveness of the rate-adaptive pacemaker by decreasing the slope of the rate-response curve. The patient will therefore not only have a limited

maximal heart rate, but will also have a lower than appropriate sensor-indicated rate beginning from exercise onset.

The under-responsiveness problem described above may be alleviated with a rate response curve that maps the long-term maximum exertion level to an age-predicted maximal heart rate or other specified maximal rate that is deemed physiologically favorable, referred to as the MAR. The specified MSR is then used only as a hard limit value for the sensor indicated rate and has no effect on the slope of the rate response curve or in the determination of the daily average maximum exertion level, long-term maximum exertion level, STR, or HRB. If the value of the MAR is less than the value of the MSR, the patient will thus never be paced at a rate corresponding to the MAR even when exercising at peak capacity. The MAR is used to establish the slope of the rate response curve so that the responsiveness of the pacemaker is not compromised by an initially low MSR value until an exertion level demanding a heart rate equal to the MSR is reached. In one embodiment, the MSR may be initially specified as a discounted percentage of the MAR and then gradually raised to the MAR over a specified length of time. For example, the MSR may be programmed as follows:

First month:	MSR = LRL + 75% of (220 - age - LRL)
Second month:	MSR = LRL + 90% of (220 - age - LRL)
Third month and thereafter:	MSR = 220 - age

The MSR can thus be set at a rate that avoids possible overpacing while the pacemaker is automatically determining the patient's maximum exercise capacity but without causing a lower than appropriate sensor indicated rate at exertion levels less than those that would be mapped to rates above the MSR.

Although the invention has been described in conjunction with the foregoing specific embodiment, many alternatives, variations, and modifications will be apparent to those of ordinary skill in the art. Such alternatives, variations, and modifications are intended to fall within the scope of the following appended claims.

What is claimed is:

1. A method for operating a rate-adaptive pacemaker wherein measured exertion levels in the patient are mapped to a sensor indicated rate by a rate response curve, comprising:

automatically determining the patient's maximum exercise capacity as defined by a long-term maximum exertion level by collecting maximum measured exertion levels over a specified period of time;

wherein the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR;

limiting the rate mapped by the rate response curve to a specified maximum sensor indicated rate MSR that is independent from the MAR; and,

increasing the MSR after a specified period time during which the long-term maximum exertion level is updated.

2. The method of claim 1 wherein the MSR is gradually increased to equal the MAR.

3. The method of claim 2 further comprising:

collecting daily maximum exertion levels;

periodically updating a long-term maximal exertion level of the patient to equal a maximum among the collected daily maximum exertion levels during a specified time period; and,

adjusting the slope of the rate response curve in order for the updated long-term maximal exertion level to be mapped to a specified maximum sensor indicated rate.

4. The method of claim 3 wherein the collected daily maximum exertion levels are maximums among moving averages of the exertion levels measured during a day.

5. The method of claim 3 wherein the rate response curve is a dual-slope curve with a slope that changes from a low rate response factor to a high rate response factor at a heart rate breakpoint that is computed as a percentage of the patient's rate reserve.

6. The method of claim 5 wherein and the rate response curve is adjusted by increasing or decreasing the low rate response factor.

7. The method of claim 5 wherein the high rate response factor is adjusted to map the patient's long-term maximum exertion level to the maximum sensor indicated rate.

8. The method of claim 5 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a fixed percentage of the rate reserve.

9. The method of claim 5 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a dynamic percentage of the rate reserve that changes in accordance with changes in the long-term maximum exertion level.

10. The method of claim 5 wherein the percentage of the patient's rate reserve used to compute the heart rate breakpoint is increased or decreased by the percentage increase or decrease, respectively, in the long-term maximum exertion level as a result of updating.

11. The method of claim 1 further comprising:

collecting daily maximum exertion levels and daily maximum sensor indicated rates;

computing weekly averages of the daily maximum exertion levels and sensor indicated rates;

computing a sensor target rate as a function of the weekly average daily maximum exertion level and the patient's maximum exercise capacity as defined by a long-term maximum exertion level; and,

periodically adjusting the slope of the rate response curve in accordance with the difference between the weekly average maximum sensor indicated rate and the sensor target rate.

12. The method of claim 11 wherein the sensor target rate is computed as a mapping from a maximum exertion level to a percentage of the patient's maximum allowable heart rate.

13. The method of claim 12 wherein a maximum exertion level is mapped to a percentage of the patient's maximum allowable heart rate in accordance with discrete thresholds relative to the patient's maximum exercise capacity in order to compute a sensor target rate.

14. The method of claim 11 wherein the slope of the rate response curve is adjusted by a specified step amount so as to increase or decrease the responsiveness of the pacemaker in accordance with whether the weekly average maximum sensor indicated rate is lesser or greater, respectively, than the sensor target rate.

15. A system for operating a rate-adaptive pacemaker wherein measured exertion levels in the patient are mapped to a sensor indicated rate by a rate response curve, comprising:

means for automatically determining the patient's maximum exercise capacity as defined by a long-term maximum exertion level by collecting maximum measured exertion levels over a specified period of time, wherein the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate, MAR;

means for limiting the rate mapped by the rate response curve to a specified maximum sensor indicated rate MSR that is independent from the MAR; and,

means for increasing the MSR after a specified period time during which the long-term maximum exertion level is updated.

16. The system of claim 15 wherein the MSR is gradually increased to equal the MAR.

17. The system of claim 15 further comprising:

means for collecting daily maximum exertion levels;

means for periodically updating a long-term maximal exertion level of the patient to equal a maximum among the collected daily maximum exertion levels during a specified time period; and,

means for adjusting the slope of the rate response curve in order for the updated long-term maximal exertion level to be mapped to a specified maximum sensor indicated rate.

18. The system of claim 17 wherein the collected daily maximum exertion levels are maximums among moving averages of the exertion levels measured during a day.

19. The system of claim 17 wherein the rate response curve is a dual-slope curve with a slope that changes from a low rate response factor to a high rate response factor at a heart rate breakpoint that is computed as a percentage of the patient's rate reserve.

20. The system of claim 19 wherein and the rate response curve is adjusted by increasing or decreasing the low rate response factor.

21. The system of claim 19 wherein the high rate response factor is adjusted to map the patient's long-term maximum exertion level to the maximum sensor indicated rate.

22. The system of claim 19 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a fixed percentage of the rate reserve.

23. The system of claim 19 wherein the slope of the rate response curve is adjusted with the heart rate breakpoint maintained as a dynamic percentage of the rate reserve that changes in accordance with changes in the long-term maximum exertion level.

24. The system of claim 19 wherein the percentage of the patient's rate reserve used to compute the heart rate breakpoint is increased or decreased by the percentage increase or decrease, respectively, in the long-term maximum exertion level as a result of updating.

25. A processor-readable storage medium having processor-executable instructions for performing the method recited in claim 1.

IMPROVED RATE-ADAPTIVE THERAPY WITH AUTOMATIC LIMITING OF MAXIMUM PACING RATE

Abstract

A system and method for automatically adjusting the operating parameters of a rate-adaptive cardiac pacemaker in which maximum exertion levels attained by the patient are measured at periodic intervals and stored. The stored maximum exertion levels may then be used to update a long-term maximal exertion level, and the slope of the rate-response curve is adjusted to map the updated long-term maximal exertion level to a maximum allowable pacing rate. In accordance with the invention, the rate response curve is defined such that an exertion level corresponding to the patient's maximum exercise capacity would be mapped to a physiologically favorable maximum rate that is independent from a specified maximum sensor indicated rate.

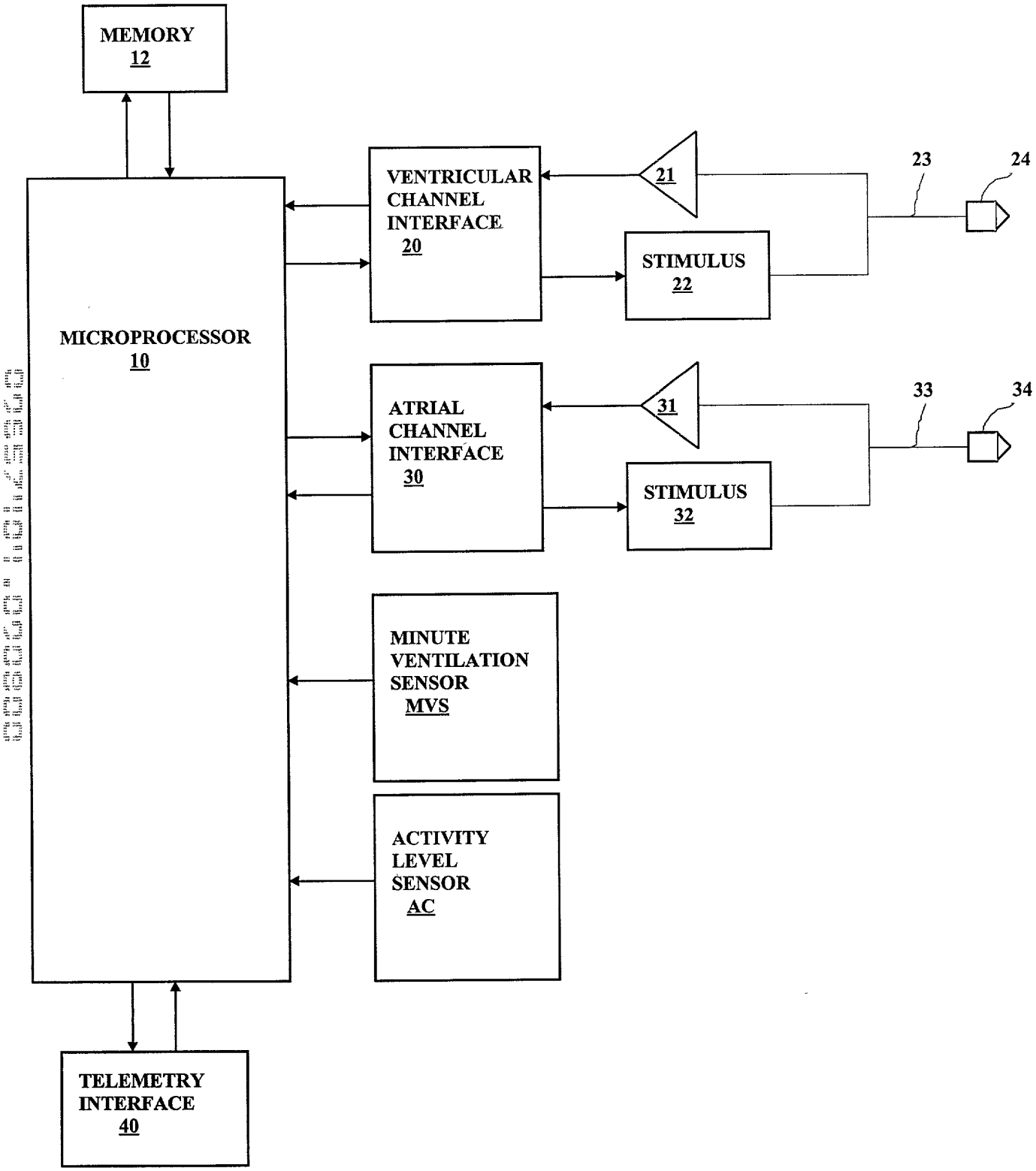
MEMORY
12
MICROPROCESSOR
10
VENTRICULAR
CHANNEL
INTERFACE
20
21
23
24
STIMULUS
22
ATRIAL
CHANNEL
INTERFACE
30
31
33
34
STIMULUS
32
MINUTE
VENTILATION
SENSOR
MVS
ACTIVITY
LEVEL
SENSOR
AC
TELEMETRY
INTERFACE
40

FIG. 1A

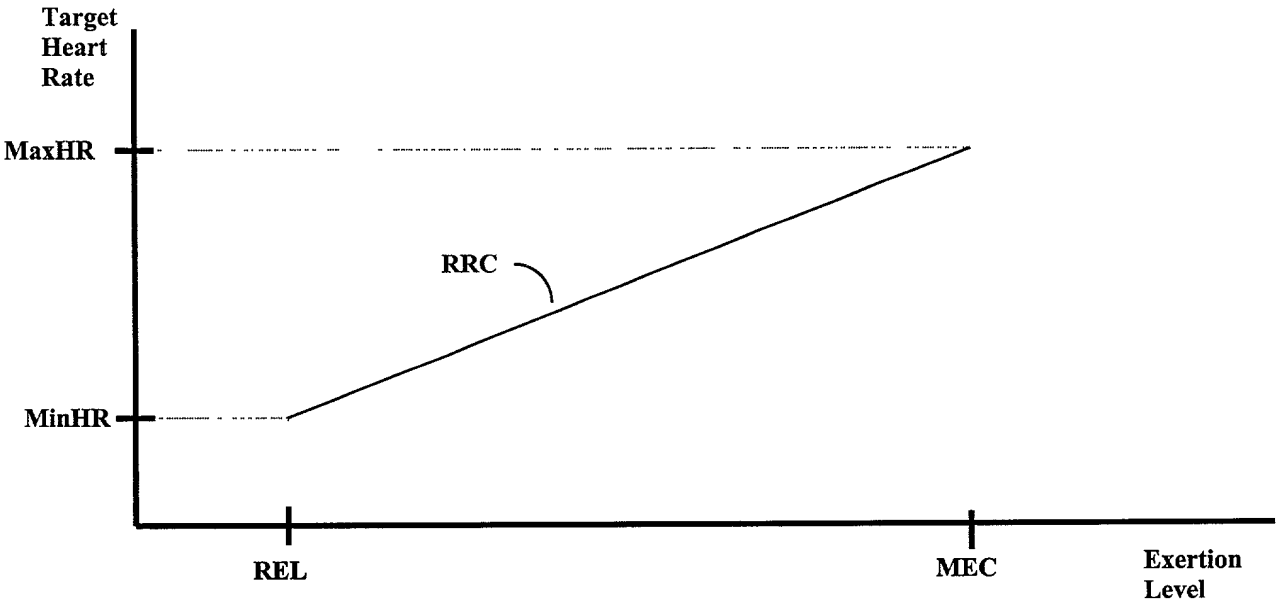

Fig. 1B

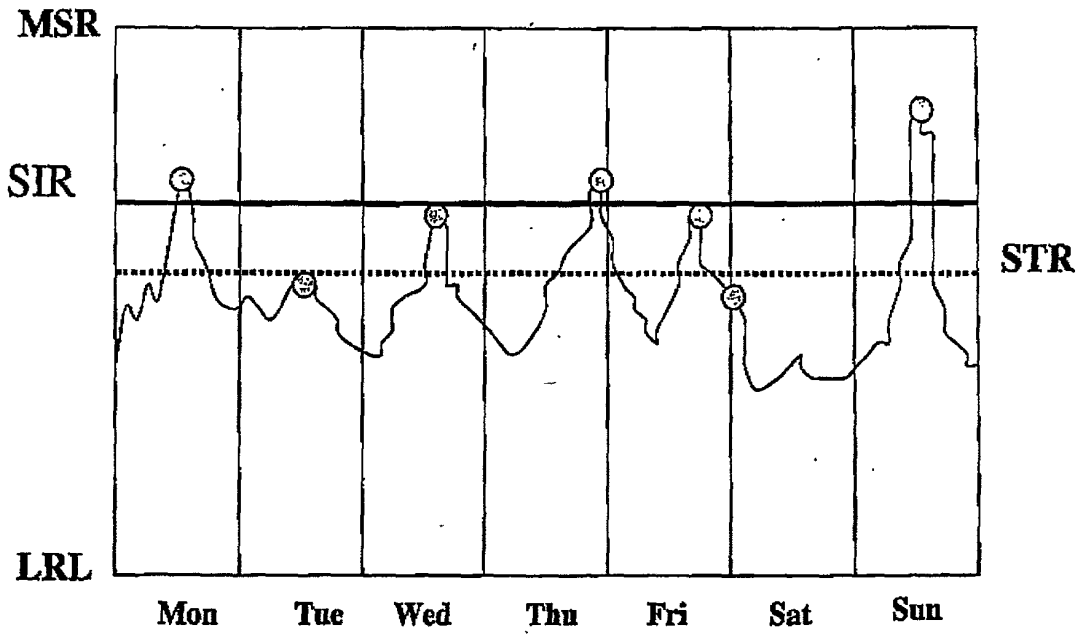

Fig. 1

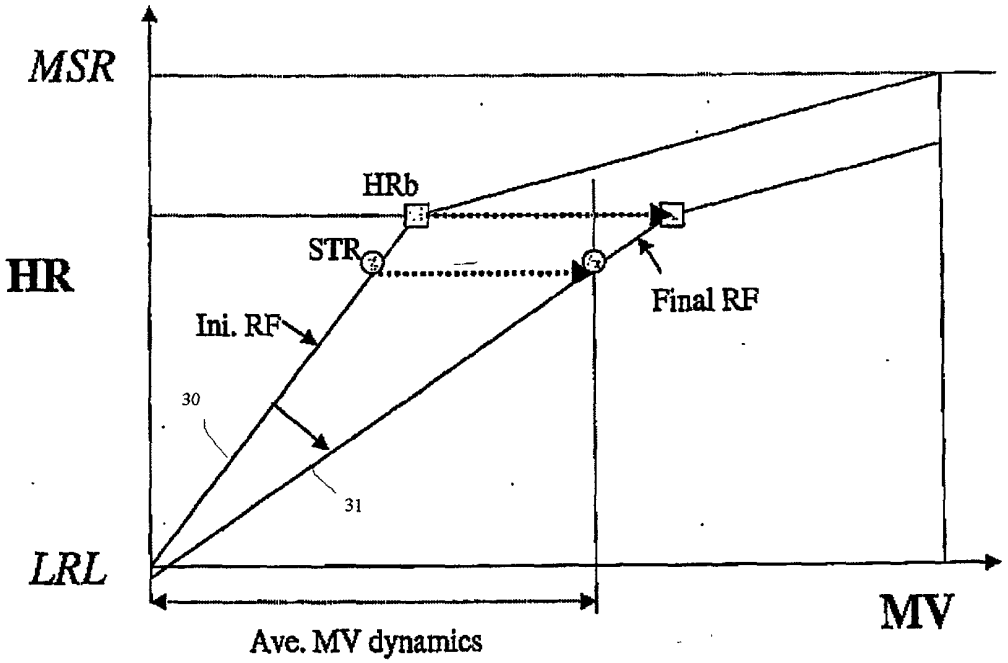

Fig.3

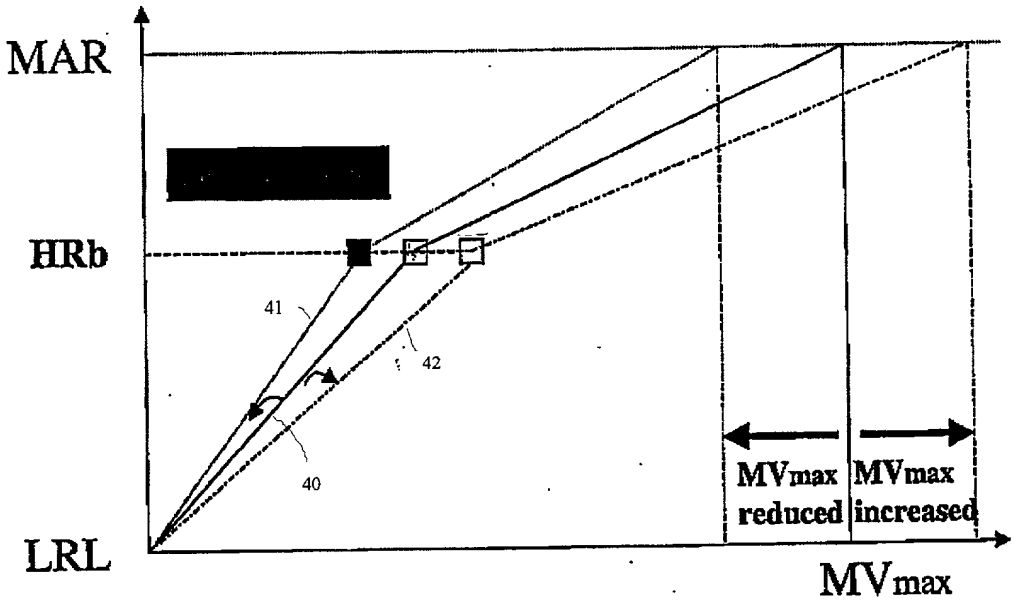

Fig. 4

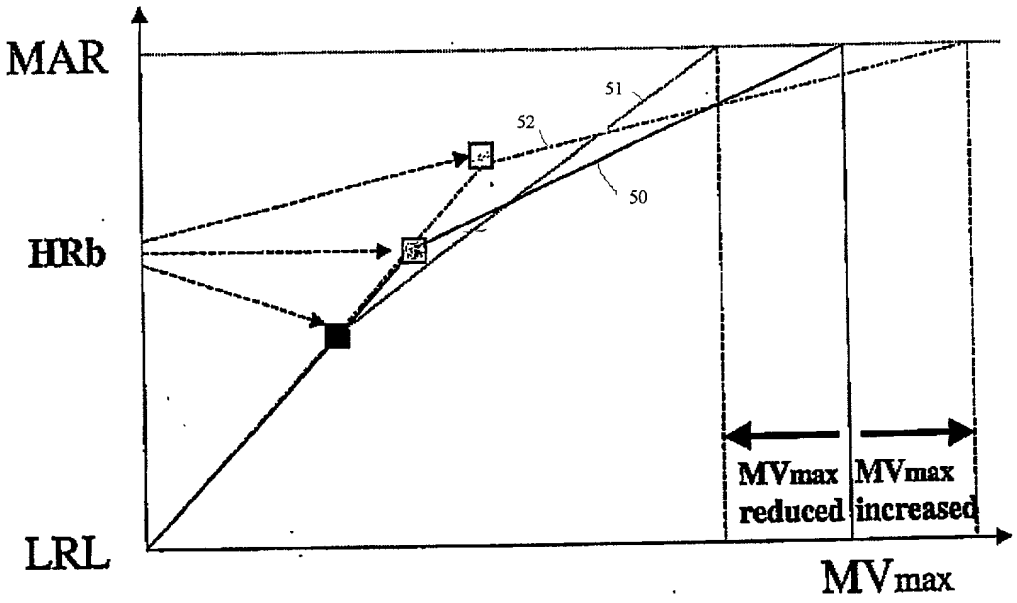

Fig. 5

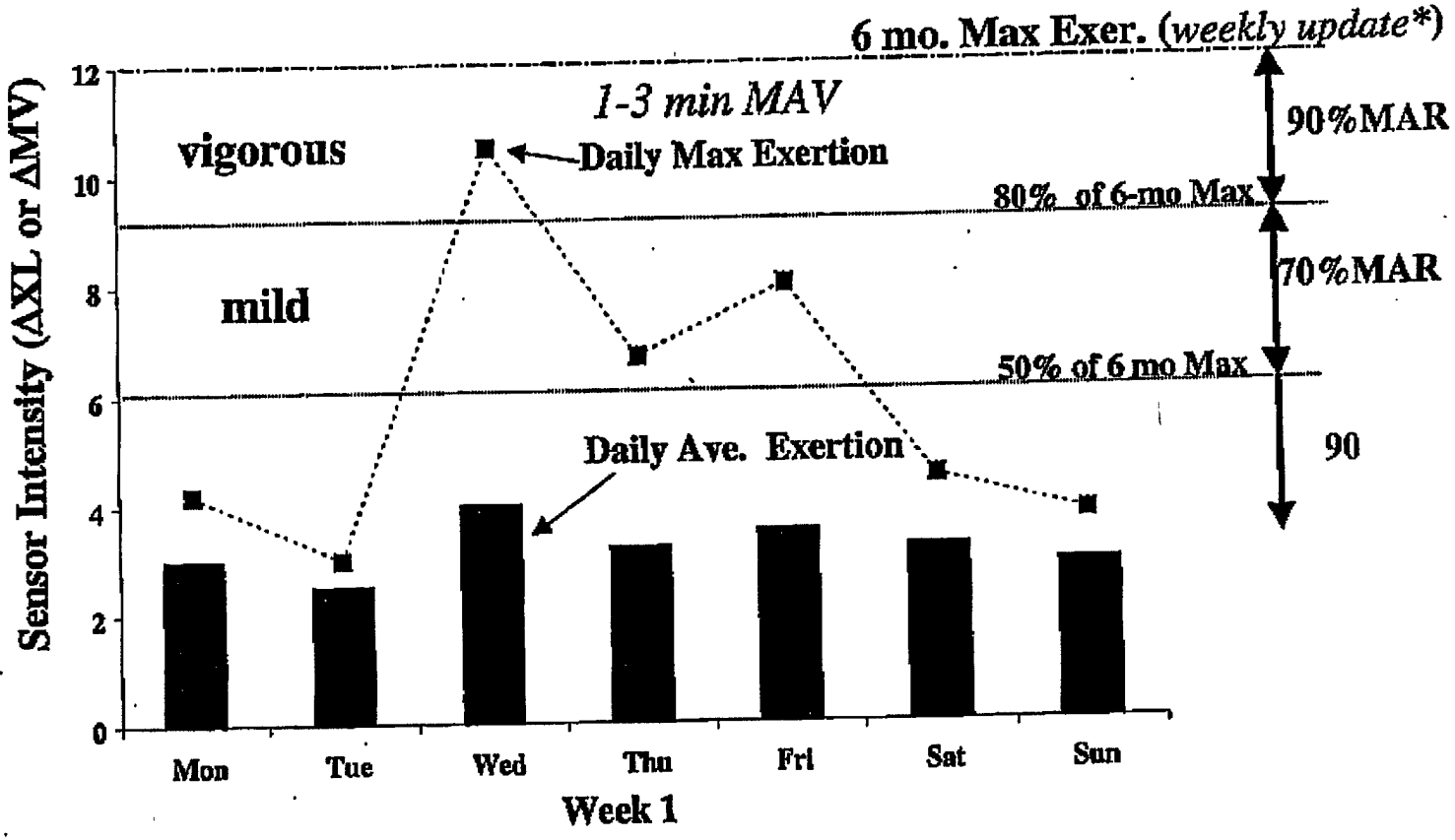
6 mo. Max Exer. (weekly update*)
1-3 min MAV
vigorous
Daily Max Exertion
90%MAR
80% of 6-mo Max
70%MAR
mild
50% of 6 mo Max
90
Daily Ave. Exertion
Sensor Intensity (ΔXL or ΔMV)
12
10
8
6
4
2
0
Mon
Tue
Wed
Thu
Fri
Sat
Sun
Week 1

Fig. 6

SCHWEGMAN ■ LUNDBERG ■ WOESSNER ■ KLUTH

United States Patent Application

COMBINED DECLARATION AND POWER OF ATTORNEY

As a below named inventor I hereby declare that: my residence, post office address and citizenship are as stated below next to my name; that

I verily believe I am the original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled: **IMPROVED RATE-ADAPTIVE THERAPY WITH AUTOMATIC LIMITING OF MAXIMUM PACING RATE**.

The specification of which is attached hereto.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with 37 C.F.R. § 1.56 (attached hereto). I also acknowledge my duty to disclose all information known to be material to patentability which became available between a filing date of a prior application and the national or PCT international filing date in the event this is a Continuation-In-Part application in accordance with 37 C.F.R. §1.63(e).

☐ I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or 365(b) of any foreign application(s) for patent or inventor's certificate, or 365(a) of any PCT international application which designated at least one country other than the United States of America, listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on the basis of which priority is claimed:

No such claim for priority is being made at this time.

☐ I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

No such claim for priority is being made at this time.

I hereby claim the benefit under 35 U.S.C. § 120 or 365(c) of any United States and PCT international application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose material information as defined in 37 C.F.R. § 1.56(a) which became available between the filing date of the prior application and the national or PCT international filing date of this application:

No such claim for priority is being made at this time.

I hereby appoint the following attorney(s) and/or patent agent(s) to prosecute this application and to transact all business in the Patent and Trademark Office connected herewith:

Anglin, J. Michael	Reg. No. 24,916	Huebsch, Joseph C.	Reg. No. 42,673	Nelson, Albin J.	Reg. No. 28,650
Bianchi, Timothy E.	Reg. No. 39,610	Jurkovich, Patti J.	Reg. No. 44,813	Nielsen, Walter W.	Reg. No. 25,539
Billion, Richard E.	Reg. No. 32,836	Kalis, Janal M.	Reg. No. 37,650	Oh, Allen J.	Reg. No. 42,047
Black, David W.	Reg. No. 42,331	Kaufmann, John D.	Reg. No. 24,017	Padys, Danny J.	Reg. No. 35,635
Brennan, Leoniede M.	Reg. No. 35,832	Klima-Silberg, Catherine I.	Reg. No. 40,052	Parker, J. Kevin	Reg. No. 33,024
Brennan, Thomas F.	Reg. No. 35,075	Kluth, Daniel J.	Reg. No. 32,146	Perdok, Monique M.	Reg. No. 42,989
Brooks, Edward J., III	Reg. No. 40,925	Lacy, Rodney L.	Reg. No. 41,136	Prout, William F.	Reg. No. 33,995
Chu, Dinh C.P.	Reg. No. 41,676	Lemaire, Charles A.	Reg. No. 36,198	Schumm, Sherry W.	Reg. No 39,422
Clapp, Richard R.	Reg. No. 31,751	LeMoine, Dana B.	Reg. No. 40,062	Schwegman, Micheal L.	Reg. No. 25,816
Clark, Barbara J.	Reg. No. 38,107	Lundberg, Steven W.	Reg. No. 30,568	Scott, John C.	Reg. No. 38,613
Clise, Timothy B.	Reg. No. 40,957	Maeyaert, Paul L.	Reg. No. 40,076	Smith, Michael G.	Reg. No. 45,368
Dahl, John M.	Reg. No. 44,639	Maki, Peter C.	Reg. No. 42,832	Speier, Gary J.	Reg. No. 45,458
Drake, Eduardo E.	Reg. No. 40,594	Malen, Peter L.	Reg. No. 44,894	Steffey, Charles E.	Reg. No. 25,179
Embretson, Janet E.	Reg. No. 39,665	Mates, Robert E.	Reg. No. 35,271	Terry, Kathleen R.	Reg. No. 31,884
Fordenbacher, Paul J.	Reg. No. 42,546	McCrackin, Ann M.	Reg. No. 42,858	Tong, Viet V.	Reg. No. 45,416
Forrest, Bradley A.	Reg. No. 30,837	Moore, Charles L., Jr.	Reg. No. 33,742	Viksnins, Ann S.	Reg. No. 37,748
Gamon, Owen J.	Reg. No. 36,143	Nama, Kash	Reg. No. 44,255	Woessner, Warren D.	Reg. No. 30,440
Harris, Robert J.	Reg. No. 37,346	Nasiedlak, Tyler L.	Reg. No. 40,099		

☐ I hereby authorize them to act and rely on instructions from and communicate directly with the person/assignee/attorney/firm/organization/who/which first sends/sent this case to them and by whom/which I hereby declare that I have consented after full disclosure to be represented unless/until I instruct Schwegman, Lundberg, Woessner & Kluth, P.A. to the contrary.

Please direct all correspondence in this case to **Schwegman, Lundberg, Woessner & Kluth, P.A.** at the address indicated below:

P.O. Box 2938, Minneapolis, MN 55402
Telephone No. (612)373-6900

☐ I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 1 : **Weimin Sun**
Citizenship: **United States of America** Residence: **Plymouth, MN**
Post Office Address: 16800 - 19th Avenue North
Plymouth, MN 55447

Signature: _____ Date: _____
Weimin Sun

Full Name of joint inventor number 2 : **Bruce R. Jones**
Citizenship: **United States of America** Residence: **Hopkins, MN**
Post Office Address: 625 Park Valley Drive West
Hopkins, MN 55343

Signature: _____ Date: _____
Bruce R. Jones

X Additional inventors are being named on separately numbered sheets, attached hereto.

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of joint inventor number 3 : **Douglas J. Lang**
Citizenship: **United States of America** Residence: **Arden Hills, MN**
Post Office Address: 4129 James Circle
Arden Hills, MN 55112

Signature: _____ Date: _____
Douglas J. Lang

Full Name of joint inventor number 4 : **Donald Hopper**
Citizenship: **United States of America** Residence: **Maple Grove, MN**
Post Office Address: 11761 99th Avenue North
Maple Grove, MN 55369

Signature: _____ Date: _____
Donald Hopper

§ 1.56 Duty to disclose information material to patentability.

(a) A patent by its very nature is affected with a public interest. The public interest is best served, and the most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. The duty to disclose information exists with respect to each pending claim until the claim is canceled or withdrawn from consideration, or the application becomes abandoned. Information material to the patentability of a claim that is canceled or withdrawn from consideration need not be submitted if the information is not material to the patentability of any claim remaining under consideration in the application. There is no duty to submit information which is not material to the patentability of any existing claim. The duty to disclose all information known to be material to patentability is deemed to be satisfied if all information known to be material to patentability of any claim issued in a patent was cited by the Office or submitted to the Office in the manner prescribed by §§ 1.97(b)-(d) and 1.98. However, no patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct. The Office encourages applicants to carefully examine:

(1) prior art cited in search reports of a foreign patent office in a counterpart application, and

(2) the closest information over which individuals associated with the filing or prosecution of a patent application believe any pending claim patentably defines, to make sure that any material information contained therein is disclosed to the Office.

(b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

(1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

(2) It refutes, or is inconsistent with, a position the applicant takes in:

(i) Opposing an argument of unpatentability relied on by the Office, or

(ii) Asserting an argument of patentability.

A prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable under the preponderance of evidence, burden-of-proof standard, giving each term in the claim its broadest reasonable construction consistent with the specification, and before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.

(c) Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

(1) Each inventor named in the application:

(2) Each attorney or agent who prepares or prosecutes the application; and

(3) Every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application.

(d) Individuals other than the attorney, agent or inventor may comply with this section by disclosing information to the attorney, agent, or inventor.